

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT DEPARTMENT  
OF THE TRIAL COURT

Civil Action No.

KATHLEEN GUZMAN,

Plaintiff,

v.

NEW ENGLAND COMPOUNDING  
PHARMACY, INC. d/b/a NEW ENGLAND  
COMPOUNDING CENTER,

Defendant.

**COMPLAINT AND JURY  
DEMAND AND  
APPLICATION FOR  
APPOINTMENT OF A  
RECEIVER**

**INTRODUCTION**

This is an action in tort (the "Complaint") brought by Kathleen Guzman (the "Plaintiff") as a result of her injection of a contaminated steroid, methylprednisolone acetate ("MPA"), that has resulted in a systemic fungal infection with a confirmed diagnosis of fungal meningitis. The MPA was compounded by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (the "Defendant" or "NECC"). As this Court is aware from the myriad of public reports, well over 450 people have been sickened and at least 32 have died. As a result, many lawsuits have already been filed against NECC, including eight suits filed in Massachusetts state courts (all of which have been removed to the District Court for the District of Massachusetts) and an additional four that have been filed in the District Court for the District of Massachusetts. Some plaintiffs have sought the attachment of NECC's property and some have sought the attachment of property of the principals of NECC. In addition to seeking

individual remedies, the Plaintiff is also seeking the appointment of a receiver for the benefit of all tort victims and creditors of NECC.

NECC is a now-defunct pharmacy located in Framingham, Massachusetts that was formerly in the business of compounding and distributing purportedly custom-mixed and otherwise not generally commercially available medications. Among other medications, NECC compounded, bottled, and distributed the sterile injectable steroid drug, MPA. During 2012, NECC shipped to various medical providers at least three lots of MPA which contained more than 17,000 doses of MPA. Eventually, the MPA in these three lots was administered to over 14,000 patients in 23 states.

In or about September 2012, state and federal public health officials became aware of an apparent outbreak of an unusual disease, fungal meningitis. Ensuing public health agency epidemiology investigations traced the source of this outbreak back to NECC's MPA product. NECC in response recalled the remaining MPA product, but as indicated, not before 14,000 doses had been epidurally administered to patients.

Beginning in October 2012, the Food and Drug Administration (the "FDA") confirmed the presence of a fungal contamination in vials of MPA that NECC has recalled and received back. Moreover, NECC's internal records showed dozens of previous instances of bacterial and fungal contamination over the past nine months, all of which NECC ignored. As reported by the Center for Disease Control and Prevention (the "CDC"), contaminated MPA compounded by NECC has already sickened 461 individuals and killed 32 people in 19 states. Dozens of lawsuits have been brought against NECC in courts throughout the country and hundreds more are expected.

As a result of the avalanche of tort claims resulting from the contaminated MPA and related events, NECC has been forced to surrender its pharmacy license, and one of the principal owners of NECC, Barry Cadden ("Mr. Cadden") and other employee, Glenn Chin ("Mr. Chin"), have temporarily surrendered their pharmacist licenses and face permanent revocation of their right to practice. Moreover, NECC has suspended its operations and laid off most of its employees. NECC and its affiliates are private family controlled entities and all of the principals involved are family members. Despite its apparent insolvency, NECC has not yet filed for bankruptcy protection under title 11 of the United States Code, and NECC's assets are in serious risk of dissipation without the appointment of a receiver. This Complaint, therefore, also seeks the immediate appointment of a receiver to manage, protect and preserve the property and assets of NECC.

### **PARTIES**

1. Plaintiff Kathleen Guzman, is an individual who resides at 1101 Carmel Road, Millville, NJ 08332.
2. Upon information and belief, Defendant New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center, is a Massachusetts corporation with its principal place of business located at 697 Waverly Street, Framingham, MA 01702.

### **STATEMENT OF FACTS**

#### **A. Formation and Corporate Governance of NECC and Affiliates**

3. NECC is a Massachusetts corporation with its principal place of business located at 697 Waverly Street, Framingham, MA 01702. It is controlled by the Conigliaro and Cadden families, with Mr. Cadden serving as President, Gregory Conigliaro ("Mr. Conigliaro") serving as Treasurer and Secretary, and Conigliaro and Cadden family members (Mr. Conigliaro, Carla Conigliaro, Mr. Cadden and Lisa Conigliaro-Cadden) comprising the entire board of directors.

4. NECC shares common ownership and corporate structure with at least two sister companies – Ameridose, LLC (“Ameridose”) and Alaunus Pharmaceutical, LLC (“Alaunus”, a wholesale distributor located on Waverly Street next to NECC). Mr. Cadden is a co-owner of Ameridose and Alaunus, and the four directors of NECC also serve as directors of Ameridose and Alaunus. The companies are private family controlled entities and all of the principals involved are family members.

5. Additionally, upon information and belief, Mr. Conigliaro owns and/or operates several other companies, including Conigliaro Industries, Inc. (a large recycling facility located next door to NECC), the real estate companies GDC Holdings Inc. and GDC Properties Management LLC.

**B. Investigations Reveal NECC Compounded Contaminated Products and Failed to Comply with State Regulations**

6. Prior to cessation of its operations in October 2012, NECC was engaged in the business of compounding, marketing, selling, and distributing various drugs. NECC distributed its products to healthcare providers across the country.

7. Under Massachusetts law, compounding pharmacies such as NECC are required to have a prescription for an individual patient in order to create (compound) a drug and are not permitted to fill bulk compounding orders. For small compounding orders, pharmacies also generally follow testing guidelines established by U.S. Pharmacopeia in order to confirm safety and efficacy of their products.

8. One of the drugs NECC compounded was the sterile injectable steroid drug known as methylprednisolone acetate (MPA). MPA is used to treat swelling and pain in the joints associated with arthritis and other joint disorders. Healthcare professionals administer MPA by injecting it into the affected location, often epidurally. In disregard of laws regulating

compounding pharmacies, including the laws of Massachusetts, NECC distributed MPA in bulk, nationwide.

9. Beginning in September 2012, reports began to surface of several patients who contracted a rare strain of fungal meningitis after receiving injections of MPA compounded by NECC. An investigation was initiated by the Massachusetts Department of Public Health (the “MDPH”) and, two days later, on September 26, 2012, NECC issued a voluntary recall of three suspect lots, containing 17,646 doses of MPA that NECC had distributed to over 14,000 patients in 23 states.

10. Also on September 26, 2012, the MDPH conducted an on-site inspection of NECC to investigate NECC’s production facilities and ensure that NECC had quarantined all remaining MPA products. In a blatant attempt to hide unsterile conditions from regulators, NECC employees were discovered cleaning the sterile compounding areas of the NECC facility and regulators also found signs of bleach decontamination. Regulators nevertheless discovered shockingly unsterile conditions. Powder hoods used to protect pharmacists from inhaling substances while working were not thoroughly cleaned as required by pharmacy safety guidelines. So-called “tacky mats” used to trap contaminants, including dirt and dust, from the shoes of employees when entering the clean room were heavily soiled with debris in violation of pharmacy safety guidelines. Standing water from a leaky boiler was in the next room over from the clean room used to compound medication. Other unsanitary conditions included rooftop HVAC units in close proximity to the Conigliaro-operated recycling facility next door, air conditioning that was turned off at night and thus failed to control temperature and humidity, and violative levels of bacteria and mold in clean rooms (as recorded even under NECC’s own environmental monitoring programs).

11. Investigators also found a bin containing 321 vials of MPA from suspect lots, 83 of which contained visible greenish-black foreign matter, and 17 of which contained white filamentous material. Of the 50 vials sent for laboratory testing, all 50 tested positive for microbial contamination.

12. Officials further discovered that, although NECC had repeatedly touted its products as sterile and high quality, NECC routinely failed to adhere to the regulatory protocols designed to ensure the sterility and safety of the drugs it was compounding and disseminating to the public. NECC was disseminating drugs without even waiting for the results of mandatory sterility tests. On at least two separate occasions, NECC shipped out vials of MPA (that were later recalled) several weeks before receiving or reviewing the results of required sterility testing. Vials from these lots of MPA, shipped and delivered to surgical centers before NECC received results from laboratories that tested their sterility, were injected into patients who subsequently developed fungal meningitis.

13. NECC was also shipping bulk quantities of compound products directly to healthcare facilities for general use rather than in response to a specific prescription, in violation of state pharmacy requirements. NECC did not have the required patient-specific prescriptions from an authorized healthcare practitioner to support its compounding and dispensation of medication as required by state law.

14. In the wake of the fungal meningitis epidemic outbreak, NECC has become subject to Congressional investigations into its and its affiliated companies' affairs and operations, revealing a long and sordid pattern of slipshod, unsanitary and dangerous processing and compounding practices and the dispensing of prescription medications in complete, wanton disregard to public health.

**C. The Plaintiff Suffers Damages as a Result of MPA Contamination**

15. The Plaintiff seeks damages resulting from the use of MPA compounded by NECC. Prior to October 5, 2012, while being treated at the South Jersey Health Care / South Jersey Hospital (the "Facility"), the Plaintiff was administered an injection of MPA which had been compounded by NECC.

16. On October 5, 2012, the Plaintiff was notified by the Facility that she had received a contaminated injection of MPA and on or about October 5, 2012, the Plaintiff visited the Facility for an examination. She was asymptomatic at this time and was sent home with instructions to return if she developed certain symptoms.

17. Several weeks later, on or about October 31, 2012, the Plaintiff recognized certain symptoms and visited the emergency room on November 1, 2012. She was then admitted to the Facility that same day. Following diagnostic testing, including a spinal tap procedure, it was determined that the Plaintiff had a systemic fungal infection with a confirmed diagnosis of fungal meningitis. The Plaintiff remained at the Facility for the treatment of fungal meningitis for five days. The Plaintiff has been discharged from the Facility as of November 6, 2012; however, continues on a treatment regime that includes medication twice a day.

18. The Plaintiff continues to exhibit certain symptoms and will continue to undergo testing. The long-term effects of the disease cannot now be definitely predicted as meningitis can result in issues such as memory loss, paralysis, hearing and vision problems, chronic headaches and speech problems.

**D. The Plaintiff and Other Victims Nationwide Suffer Damages, Including Multiple Deaths, as a Result of Meningitis Contamination**

19. As of November 9, 2012, the CDC has confirmed that the meningitis outbreak, caused by MPA compounded and distributed by NECC, has killed 32 people and sickened over 400 others.

20. To date, claimants nationwide have commenced over 40 lawsuits filed in eight different states, including twelve in Massachusetts. The number of claims against NECC is rising dramatically, with numerous additional cases likely to be filed as illnesses continue to be diagnosed and linked to NECC.

**E. NECC Shuts Down All Operations After Regulatory Actions**

21. On October 1, 2012, the MDPH issued a formal quarantine order pursuant to G.L. c. 94C, §§ 13 & 189A, and G.L. c. 112, §§ 30 & 42A, requiring NECC to preserve all products used to compound MPA, including products returned from pharmacies.

22. In response to October 2, 2012 findings from the FDA and the MDPH, the Board of Registration in Pharmacy (the "Board") voted to request a voluntary surrender of NECC's pharmacy license. NECC surrendered its license effective at noon on October 3, 2012 and further instituted a voluntary recall of all of its intrathecal medications, which are designed for injection near the spinal cord or brain.

23. The FDA and the CDC have recommended that all health care providers cease use of, and remove from inventory, any products from NECC. At the behest of the MDPH, NECC issued an immediate recall of all of its products, and Mr. Cadden and Mr. Chin surrendered their pharmacist licenses pending the outcome of the investigation. The Board has since demanded that Mr. Cadden, Mr. Chin and Lisa Conigliaro-Cadden permanently surrender their licenses voluntarily.

24. Today, NECC no longer operates or conducts any business. NECC has surrendered its pharmacy license, suspended all operations, and laid off most of its employees. One of its principals, Mr. Cadden, as well as Mr. Chin, have surrendered their pharmacist licenses and face permanent revocation of their right to practice. The MDPH also has temporarily barred former pharmacists for NECC from practicing pharmacology.

**F. The Failure of NECC's Principals to Cooperate Has Created a Total Vacuum of Information, Making NECC's Assets Ripe for the Picking**

25. NECC, acting through its principals, has repeatedly failed to cooperate with investigators and has failed to provide the Plaintiff or other creditors even the most basic of information.

26. On one occasion, Mr. Cadden lied to an FDA investigator about NECC's possession of bulk product improperly prepared in advance without a prescription, which the investigator subsequently located during an inspection. Mr. Cadden also frequently misrepresented NECC's practices and procedures to the FDA and the MDPH to avoid additional scrutiny by regulators and create a false impression of regulatory compliance.

27. Mr. Cadden has refused to voluntarily cooperate with investigations by the United States Congress into the events leading up to the outbreak and his handling of NECC's business. On November 6, 2012, Mr. Cadden was subpoenaed by the House of Representatives to appear before the Committee on Energy and Commerce, Oversight and Investigations Subcommittee (the "Committee"). On November 14, 2012, at the hearing before the Committee, Mr. Cadden invoked his Fifth Amendment privilege against self-incrimination and refused to answer any questions posed by the Committee, including whether he held an ownership interest in NECC. A reasonable inference is that any testimony Mr. Cadden would have given would have been adverse to his interest.

28. NECC has also refused to respond to informal requests by the Plaintiff's counsel for the production of existing insurance policies (both general corporate coverage, as well as director and officer coverage that potentially is available only to cover claims by NECC) that may provide a source of potential recovery for tort victims other than to indicate that existing coverage is insufficient to address all of the anticipated claims to be filed against NECC. As a result, the Plaintiff does not know the amount of coverage, nor does she know whether NECC and its principals have taken basic steps necessary in order to preserve the availability of insurance coverage.

29. Further, although Mr. Cadden has purportedly agreed to resign as manager and director of NECC, Ameridose and Alaunus, his family members have made no such agreement and as owners those families still exercise complete dominion and control over all of NECC's assets, and may continue to deploy those assets for their own personal gain at the expense of creditors.

**G. NECC's Assets are Vulnerable to Immediate Dissipation**

30. Due to the termination of NECC's operations and the failure of NECC's principals to cooperate with investigations, there is zero transparency and accountability to NECC's stakeholders regarding how NECC's assets are being administered. Despite having insufficient assets and no continuing revenues to satisfy its mounting liabilities, NECC has not filed for bankruptcy protection.

31. Although NECC's principals have succeeded in concealing the current state of its assets, given the cessation of operations and the laying off of employees, it is reasonable to infer that some or all of NECC's assets, such as cash and accounts receivable (which require at least minimal manpower to collect), are at serious risk of imminent waste.

32. Given the results of the investigations to date, it appears that there is ample reason to believe that serious breaches of fiduciary duty owed by Mr. Cadden and the other principals of NECC have occurred and may go unprosecuted in the absence of a receiver to act in the best interests of all of NECC's creditors and other constituents. To the extent that directors and officers insurance exists, that coverage may also be wasted if suit is not brought immediately, as such policies are generally claims made policies requiring the notice of a claim to the insurer within the policy period.

33. Upon information and belief, the owners and principals have also caused NECC to pay themselves millions of dollars which they have used, for example, on homes within the last year.

**H. Immediate Appointment of a Receiver is Appropriate**

34. A receiver is required to prevent additional hemorrhaging and preserve the assets for an eventual equitable distribution among NECC's creditors.

35. The Plaintiff respectfully suggests to the Court that while there are perhaps other capable professionals willing to serve, the Plaintiff has evaluated one exceptionally capable and highly experienced fiduciary, Stephen S. Gray ("Mr. Gray"), who is willing to serve in that role as a fiduciary for all concerned. Mr. Gray has served as a receiver, trustee or other fiduciary in dozens of other distressed situations over more than 37 years as New England's leading restructuring and crisis manager. Additional information related to Mr. Gray's experience is contained in the Affidavit of Stephen S. Gray in Support of Plaintiff's *Ex Parte* Motion for Appointment of a Receiver filed contemporaneously herewith.

36. Mr. Gray would maintain, preserve and protect the Receivership Estate (as defined in the [Proposed] Order for Receiver, attached as Exhibit A to Plaintiff's *Ex Parte*

Motion for Appointment of a Receiver, filed contemporaneously herewith) as well as properly market and, if necessary, liquidate the Receivership Estate fairly, efficiently and effectively.

**COUNT ONE**  
**NEGLIGENCE**

37. The Plaintiff repeats and realleges each of the foregoing allegations as if fully set forth herein.

38. As the compounder and seller of MPA, NECC had a duty to the Plaintiff to exercise reasonable care in the preparation, storage, testing, compounding and distribution of MPA and to ensure that MPA was safe for its customers.

39. NECC breached its duty by failing to exercise a reasonable degree of care, skill and diligence, including through the following acts: (i) failing to establish quality control measures; (ii) assembling a contaminated product; (iii) failing to test the MPA before its distribution; (iv) failing to recognize that the MPA was contaminated; (v) releasing a contaminated drug product into the stream of commerce.

40. NECC acted with reckless disregard towards the safety of users of the MPA.

41. The Plaintiff's injuries were directly and proximately caused by NECC's negligence.

42. The Plaintiff has suffered and will continue to suffer damages, including but not limited to medical expenses and pain and suffering. As a result of NECC's negligence, the Plaintiff has incurred and will continue to incur medical expenses for the treatment of her illness.

**COUNT TWO**  
**BREACH OF IMPLIED WARRANTY**

43. Plaintiff repeats and realleges each of the foregoing allegations as if fully set forth herein.

44. The MPA was not reasonably fit for the ordinary purposes for which the MPA is used and did not meet the expectations for the performance of the MPA when used in the customary, usual and reasonably foreseeable manner, nor was the MPA minimally safe for its expected purpose.

45. At all relevant times, the Plaintiff used the MPA for the purpose and in the manner intended by NECC.

46. The Plaintiff by the use of her reasonable care, could not have discovered the breached warranty and realized its danger.

47. The breach of the warranty was a substantial factor in bringing about the Plaintiff's injuries.

48. As the direct and proximate result of the breach of implied warranty, the Plaintiff has suffered and will continue to suffer injuries and damages including, but not limited to medical expenses and pain and suffering.

**COUNT THREE**  
**APPOINTMENT OF RECEIVER**

49. The Plaintiff repeats and realleges each of the foregoing allegations as if fully set forth herein.

50. The appointment of a receiver is necessary in order to, among other things, protect and preserve the assets and property of NECC from dissipation.

51. NECC has surrendered its license to compound and dispense pharmaceuticals. NECC has ceased day to day operations and has laid off most of its employees.

52. NECC has insufficient assets and no new business to satisfy all of the claims that have been filed against it. NECC has not filed for bankruptcy protection or otherwise taken any

steps to preserve its assets, and thus, a receiver is necessary to protect and preserve NECC's assets for an eventual equitable distribution among all of NECC's creditors.

53. As demonstrated above, the Plaintiff has valid claims against NECC.

54. Hundreds of other individuals may have similar claims against NECC based on receiving injections of the MPA compound disseminated by NECC. Numerous individual lawsuits have been filed in this state and throughout the country.

55. NECC has assets applicable to the payment of the claims against it.

56. Absent a receiver, the Plaintiff will have no adequate remedy at law. There is an imminent danger that NECC will waste its assets that otherwise would be available to satisfy the Plaintiff.

57. Moreover, the sheer volume of legal actions pending and expected to be brought will cause the wasting of NECC's assets unless a receiver is appointed with the authority to administer a rational claims resolution process.

#### **JURY DEMAND**

The Plaintiff hereby demands trial by jury on all counts so triable.

#### **DEMAND FOR RELIEF**

WHEREFORE, the Plaintiff respectfully request this Court enter judgment in its favor against the Defendant:

- a) Entering judgment against the Defendant in favor of the Plaintiff;
- b) Awarding the Plaintiff damages to be proven at trial;
- c) Awarding all costs and expenses, including attorneys' fees as provided by law;
- d) Appointing Stephen S. Gray as receiver to take possession of the Receivership Estate in order to, among other things, manage, preserve and possibly liquidate

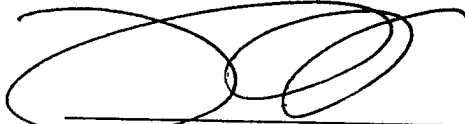
the Receivership Estate and collect and marshal all assets for the benefit of the Receivership Estate;

- e) Granting such other and further relief as this Court deems fair and equitable.

Respectfully submitted,

KATHLEEN GUZMAN

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